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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,829	05/15/1998	ALAN D. SNOW	PROTEO.P07	8764

7590 07/02/2002

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ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/02/2002

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 26

Application Number: 09/079,829
Filing Date: May 15, 1998
Appellant(s): SNOW ET AL.

Patrick M. Dwyer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 24, 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-13 and 44-54 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,940,725 KEPLINGER et al. 07-1990

Stuppner, et al. "HPLC Analysis of the Main Oxindole Alkaloids from Uncaria tomentosa" Chromatographia, vol. 34, no. 11/12, (December 1992), pp. 597-600.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 5, 6, 9, 47, and 50 stand finally rejected under 35 U.S.C. 112, second paragraph, for the reasons of record set forth on page 2 of the Office action of April 24, 2001, Paper No. 18.

Claims 5, 6, 9, 47, and 50 are rendered indefinite by the use of parentheses. The use of parentheses is considered indefinite because it cannot be determined when the enclosed limitation is or is not to be included in the claim. It is unclear when or if the material in the parentheses is to function as a limitation of the claim; therefore, the meets and bounds of the claims cannot be definitely determined. The use of the parentheses creates confusion and is improper.

The use of parentheses in the chemical names found in claims 6 and 47 is not considered improper because this is common chemical notation; however, the additional parentheses in these claims that are not associated with chemical names are considered indefinite for the stated reasons.

Claims 1-10, 12, 13, 44-51, 53, and 54 stand finally rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 4,940,725 for the reasons set forth on pages 2 and 3 of the Office action of April 24, 2001, Paper No. 18.

Appellant's claims are drawn to a composition comprising plant matter from a plant of the genus *Uncaria*. The species is *Uncaria tomentosa*. The extract is coupled with a pharmaceutical carrier.

US '725 anticipates the stated claimed because US '725 teaches an oral pharmaceutical product extracted from the root parts of *U. tomentosa*. The extract contains oxindole alkaloids

and is administered in a pharmaceutical carrier (see claims 1, 6, and 11). US '725 teaches that the plant extract can be administered safely in a dosage form up to 5 g/kg body weight (see column 17, lines 60-65).

US '725 does not teach administering the *Uncaria tomentosa* extract for treating amyloid diseases as claimed by applicant; however, because the composition of US '725 is identical to the claimed composition, the composition of US '725 would inherently have the same effects on the human body as the claimed composition. Furthermore, these limitations appear in the preamble of applicant's claims. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The uses of the composition recited in the claim are considered recitations of intended use. Recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1-6, 9, 10, 12, 13, 44-47, 50, 51, 53, and 54 stand finally rejected under 35 U.S.C. 102(b) as being anticipated by Stuppner et al. (Chromatographia (Dec, 1992) vol. 34, no.

11/12, pp. 597-600) for the reasons set forth on pages 3 and 4 of previous Office action of April 24, 2001, Paper No. 18.

Stuppner anticipates the stated claims because Stuppner teaches a pharmaceutical composition of decoctions of *U. tomentosa* bark (see page 597, first paragraph). Stuppner reports that the bark extracts contain oxindole alkaloids.

Stuppner does not teach administering the *Uncaria tomentosa* extract for treating amyloid diseases as claimed by applicant; however, because the pharmaceutical composition described by Stuppner is identical to the claimed composition, the composition of Stuppner would inherently have the same effects on the human body as the claimed composition. Moreover, these limitations appear in the preamble of applicant's claims. As stated in the above 102(b) rejection, limitations in the preamble are not given patentable weight when they merely recite intended uses of a product fully described in the body of the claim. In addition, the stated uses for the composition are considered recitations of intended use. Recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1-3, 11, 44-46, and 52 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,940,725 for the reasons set forth on page 4 of the Office action of April 24, 2001, Paper No. 18.

As stated above, US '725 anticipates an extract of *U. tomentosa*; however, US '725 does not teach a composition that contains 70 to 95% *U. tomentosa*. The amount of an active ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize particularly because US '725 teaches a wide range of concentrations which are therapeutically active. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been routine for an artisan of ordinary skill to determine the optimal amount of *U. tomentosa* to use in the composition in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of the amount of *U. tomentosa* would have been obvious at the time of applicant's invention.

Claims 1-3, 11, 44-46, and 52 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Stuppner et al. for the reasons set forth on pages 4 and 5 of the Office action of April 24, 2001, Paper No. 18.

As stated above, Stuppner anticipates an extract of *U. tomentosa*; however, Stuppner does not teach a composition that contains 70 to 95% *U. tomentosa*. The amount of an active ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been routine for an artisan of ordinary skill to determine the optimal amount of *U. tomentosa* to use in the composition in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of the amount of *U. tomentosa* would have been obvious at the time of applicant's invention.

(11) Response to Argument

The appellant argues against the 112, second paragraph, rejection by stating that the use of parentheses is not indefinite because the appellant has stated that the limitations within the parentheses are to be included as limitations in the claims. However, even if the material enclosed in the parentheses are intended to be limitations on the scope of the claim, it is unclear when these limitations must be met. The use of parentheses is similar to the use of "such as" or "for example" which is clearly indefinite because it cannot be definitely determined when the limitations are given weight. The parentheses lead to confusion over the intended scope of the claims. Therefore, for these reasons, the use of parentheses in the claims in considered indefinite.

Regarding the 102(b) rejection over US Pat. No. 4,940,725, the appellant argues US '725 does not teach the claimed invention because US '725 does not teach that the oxindole alkaloid containing extract of *Uncaria tomentosa* is able to inhibit amyloid fibrils or to treat amyloid disease. The appellant contends that the ability to inhibit amyloid fibrils and to treat amyloid diseases would not be inherent in the composition taught by US '725. The appellant also argues that the intended use should be given patentable weight because the intended use is recited in the body of the claim.

The examiner disagrees the appellant for the following reasons. The appellant's claims are drawn to a pharmaceutical *agent*, a product, *not* a method of administering an agent to treat a disease. It is a well established principle that if the product is known then a recitation of intended use does not distinguish the claimed composition from the composition of the prior art if the product are identical. The appellant offers no evidence or argument that shows that the

product of US '725 is different than the claimed product. In fact, page 4 of the appellant's specification cites US '725 as teaching that the claimed phytochemicals can be isolated from *U. tomentosa*. Thus, the composition of US '725 is clearly the same product as that claimed by the appellant. In addition, US '725 teaches administering the *U. tomentosa* extract in the same amounts as those claimed by the appellant (see column 17, lines 25-end of US '725). Since the prior art teaches administering same composition in the same amounts as claimed, the prior art would *clearly* have to inherently function in the manner claimed by the appellant. If the composition of US '725 does not function in the same manner, then the appellant's invention would not function as claimed. The appellant argues that *In re Robertson* and *In re Shetty* support the appellant's arguments that the prior art must show to a degree that a person of ordinary skill in the art would recognize that the prior art agent inherently possess the properties of the claimed agent. However, neither *Robertson* nor *Shetty* deal with inherent properties of pharmaceutical agents that are identical except for the intended use of the agents. Therefore, these cases are not relevant to the matter at hand.

Appellant's agent is not disclosed or argued to be a novel compound, a combination of novel compounds, a novel combination or a novel composition. In fact, in claims 4-5 (and in the specification) the appellant sates that the agent is commercially available. The active ingredients in the agent are not novel. Additionally, the appellant has disclosed that the therapeutically effective concentration of the agent is not specific, wide ranges are disclosed. Thus, the appellant's agent is clearly disclosed by the prior art of record because said prior art clearly discloses the appellant's agent as it clearly discloses the same *Uncaria* plant matter, extracts thereof, and active compounds thereof in pharmaceutical composition. The effective

amounts claimed by the appellant are encompassed by the concentrations taught by the prior art. The product claimed is clearly the same product taught by the prior art.

Regarding the 102(b) rejection over Stuppner, the appellant states that the arguments against US '725 are the same arguments that are applicable against this reference. Therefore, the examiner disagrees with the appellant for the reasons explained above. The composition of Stuppner is the same as the claimed composition. Therefore, the claimed composition is not patentable over Stuppner.

Regarding the 103(a) rejection over US '725, the appellant argues a person of ordinary skill in the art would not be motivated to modify the dosages taught by US '725 because a specific reference has not been cited to support the examiner's statement that it is a routine practice to optimize the dosages in a pharmaceutical composition. However, this principle is extremely well known in the art. Routine optimization is an ordinary skill in the art. Changing the dosage of a pharmaceutical substance is a practice that occurs every day in medical research and in the medical practice. In addition, US '725 teaches that the dosage can be modified (see column 17, lines 62-67). The case cited by appellant to support this point, *In re Yates,* is not related to optimizing the dosages in a pharmaceutical composition. Therefore, it is not considered relevant to the matter at hand.

In addition, the appellant argues that optimization of the dosage should not occur when the claims are novel. However, the claims are not considered novel for the reasons stated above.

The appellant argues the 103(a) rejection over Stuppner together with the arguments against US '725. Therefore, the same arguments made by the examiner are applicable here.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

SDC
June 27, 2002

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